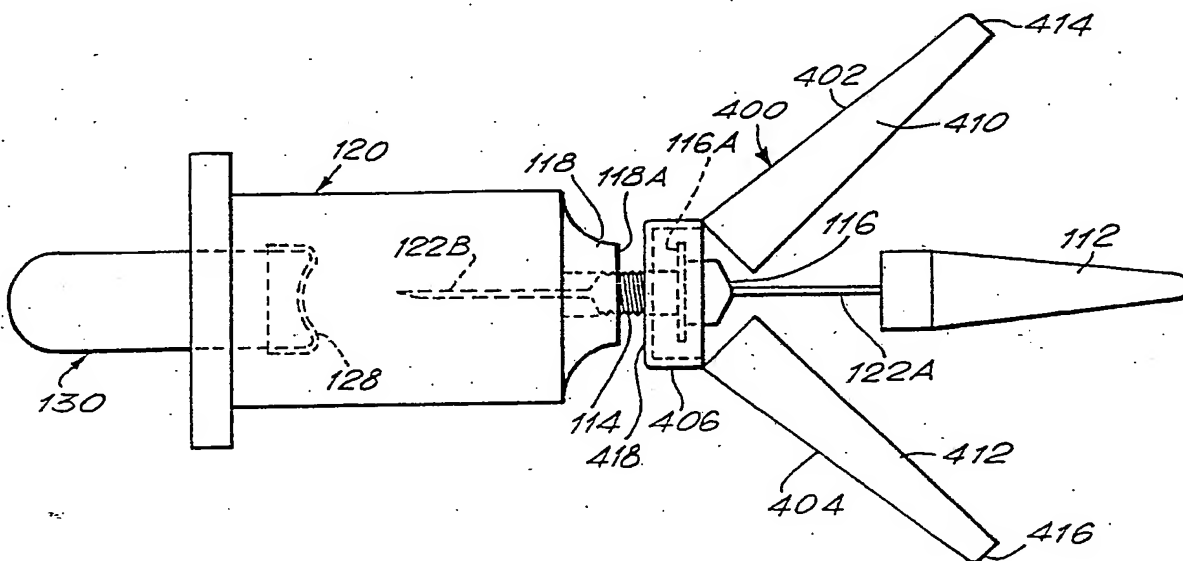




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61M 5/32, A61B 5/14	A1	(11) International Publication Number: WO 91/09638 (43) International Publication Date: 11 July 1991 (11.07.91)
(21) International Application Number: PCT/GB90/01993 (22) International Filing Date: 20 December 1990 (20.12.90) (30) Priority data: 8928957.3 21 December 1989 (21.12.89) GB 9004239.1 26 February 1990 (26.02.90) GB (71)(72) Applicant and Inventor: STEER, Andrew, William [GB/ GB]; 94A Bushey Hill Road, Camberwell, London SE5 8QQ (GB). (74) Agent: COOK, A., J.; D. Young & Co., 10 Staple Inn, Lon- don WC1V 7RD (GB).		(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GR (Euro- pean patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI pa- tent), US. Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: METHOD AND APPARATUS FOR BLOOD SAMPLING



(57) Abstract

A blood sampling kit comprising an open ended syringe barrel (120), a double ended needle (122) having a central boss (116) and one end closable by a removable sleeve, a blood sample receiver (130) closed by a puncturable membrane (128) and containing sterile gas at a pressure substantially negative relative to atmospheric, and a needle protector having a central part attached to or clipped on to the central boss (116), the protector (400) being hingeable between closed and open positions and when closed defining a substantially closed chamber for containing part of a needle.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark				

METHOD AND APPARATUS FOR BLOOD SAMPLING

This invention relates to a needle protector and a method of using a needle protector in the extraction of a blood sample from a patient.

In my U.K. Patent Application numbers 8928956, 7 and 9, needle protectors are disclosed having a central part and two housing parts which can be folded together to a mutually closed position and moved apart to expose the needle.

One of the major risks of contracting or spreading the HIV virus or Hepatitis occurs when blood sampling takes place. A major supplier of a blood sampling system in U.K. is Becton Dickinson. Their system is known as the "Vacutainer" system. A needle protector according to U.K. Patent Application No. 89 28957 or 9 can be used without modifying their system.

According to the present invention, it is possible to employ such a needle protector, and secure the advantages of avoidance of needle stick injuries and prevention of second use of needles, when the needles are used in an established "Vacutainer" system of withdrawing a blood sample from a patient.

According to one aspect of the invention, there is provided a blood sampling kit comprising:-

an open ended syringe barrel, a double ended needle having a central boss and one end closable by a removable sleeve, a blood sample receiver closed by a puncturable membrane and containing sterile gas at a pressure substantially negative relative to atmospheric, and a needle protector having a central part attached to or clipped on to the central boss, the protector being hingeable between closed and open positions and when closed defining a substantially closed chamber for containing part of a needle.

The invention will be better understood from the following description of a preferred embodiment thereof, given with reference to the following particular description and accompanying illustrative drawings, in which:-

Figures 1-4 illustrate the use of the established "Vacutainer" system;

Figures 5-12 are views of an embodiment of needle protector shown in U.K. Patent Application No. 89 28959. Note that in the description of these figures the reference numerals employed are those of the '959 application.

-2-

Figure 13 illustrates the protector assembled together with components of the "Vacutainer" system for operating a method according to the present invention.

The "Vacutainer" system includes a syringe barrel and a needle holder containing a double ended needle, one end of which is covered with a rubber closed-ended sleeve. The needle has a passageway completely therethrough. One end of the needle is closed by the rubber sleeve. There is also a protective cap for each end of the needle. The needle holder is threaded to engage within a complementary internal thread on one end of a syringe barrel which has an open rear end. In addition there is a glass or plastics sample receiver whose top is covered by a puncturable membrane for example, made of rubber. This receiver is sterile and contains a vacuum.

In the conventional use of this system the nurse or user takes the needle holder packet, removes the cap from one end to expose the rubber covered needle and then screws the threaded portion into the threaded (front end) part of the syringe. The cover protecting the opposite end of the needle is then removed and this end of the needle inserted into the person from whom the blood sample is to be taken. The receiver is then pushed onto the other end of the needle, so causing that end of the needle to puncture firstly the end of the sleeve and then the rubber membrane. The interior of the passageway through the double needle is thus subjected to the strong negative pressure within the receiver and blood is consequently sucked out of the patient and into the receiver.

At this time, according to present conventional procedure, the nurse or medical auxiliary or practitioner has to replace the needle packaging in order to cover the used needle; during this process there is a high probability of stick injuries. By the use of a method according to the present invention, the chance of such injuries is greatly reduced. Prior to the threading of the needle holder into the syringe, the central part of a needle protector according to any one of U.K. Patent Application Nos. 8928956, 8928957 and 8928959 is clipped or snapped onto a suitable portion of the needle holder (needle boss), in the same way as a needle protector is clipped on to a syringe nozzle as described in any

-3-

one of the said three U.K. patent applications.

Referring now to Figures 1-4, Figure 1 shows a needle holder containing a doubled-ended needle, each end of which is completely enclosed by a protective cap. One such cap 110 (the left hand end as in Fig. 1) is fitted on by screwthreading onto a threaded part 114 and the other cap 112 is a push fit over a central boss 116 from which the part 114 projects. The hollow metal double needle 122 passes through the centre of this boss 116. Figure 2 illustrates the lefthand cap 110 being withdrawn after being unthreaded. The threaded part is then screwed into a threaded collar 118 of the syringe-like holder 120. The next stage in the use of the conventional "Vacutainer" system is the pulling off of the other cap 112 to expose the needle portion 122A ready to insert into the patient from whom a sample is to be taken. The sample is taken by pushing the receiver 126 onto the needle portion 122B within the syringe body. In this operation the needle portion 122B punctures both the rubber sleeve thereon (not illustrated in fig. 13) and the membrane 128 (seen in Fig. 13). Due to the reduced pressure in the receiver, blood is thus sucked into the sample receiver 130. Of course the forward end of the receiver 130 is closed by the membrane 128 until it is punctured.

In one advantageous modification, the threaded part of needle boss 116 could be reconstructed or lengthened to permit the needle protector to be assembled conjointly with the double needle and to serve as a protector for the needle during storage, delivery, and prior to use.

In the description from this point onwards, until the end of the description of Figs. 11 and 12, the reference numerals used are those on Figs. 5-12.

Referring now to Figures 5-9, the illustrated needle protector is integrally moulded from a synthetic plastics material such as polypropylene, and has a first housing part 10, a second housing part 20, and a central part 30. The parts 10 and 20 are connected to the part 30 by integral plastics hinges 11 and 21. The first housing part 10 has a base 12, side walls 13, and a wall 14 at its free end which carries a latch portion 15 of a latching means. A needle support structure is formed by a wall 17 which is shaped generally as a saddle. In use this wall in conjunction with the wall 27 (to be later described) locates the

-4-

needle shank when the parts 10, 20 are in their mutually closed condition. The part 10 also has a low wall 16 near the hinge which helps to stiffen and reinforce the structure of the housing. This reinforcement is desirable because the walls are fairly thin, since it is important to save material in a "throw-away" product. The second housing part 20 has a base wall 22, side walls 23, and a free end wall 24. It also has a low wall 26 at the end by which it is joined to the central part 30. An intermediate saddle shaped wall 27 serves as a needle locator and support in a similar way to the wall 17. At the free end, i.e. the end remote from the central part 30, the second housing part 20 has an aperture 25 which serves as a co-operating portion of the latching means. The aperture 25 is preferably approximately rectangular as seen in Figures 5 and 6. There is a thinned portion 25a of synthetic plastics material adjacent thereto. In use, this portion is deformed by entry of the latch member 15 into the aperture 25. After entry of the latch the portion 25a tends to spring back to its normal position, due to the resilience of the plastics from which the protector is made, so preventing or tending to prevent an opening of the coupled housing parts 10 and 20 even if the latch 15 should chance to be forced (e.g. by an accidental impact) in a direction towards the central part 30. The second housing part 20 also includes side plates 29 whose function is to assist in aligning the two housing parts when they are folded into their mutually closed condition.

As shown, the central part 30 is a simple rectangular or square cup shaped plastics member joined by integral hinges 11 and 21 to the housing parts 10 and 20. Its thickness is chosen to be suitable to the relevant dimensions of the threaded portion see (Fig. 13) of boss 16. Central parts of other suitable shapes however may be employed. There is a keyhole slot 31 in the central part 30 as best seen in Figures 5 and 6. The central portion 32 of this slot is preferably circular.

While it is preferred to have a keyhole slot as illustrated at 31 and 32, the invention must not be regarded as limited to this feature. A needle protector according to the invention would work almost as well if it had merely a slot of different shape permitting the protector to be clipped or snapped onto the holder (boss 116). The thickness of the wall portion 34 of the central part 30

-5-

can be increased. With the construction as illustrated, this thickness would normally be around 1 mm. to 2 mm., but it can be increased to about 3 mm. to 4 mm., or decreased, if desired. For larger needle bosses, of course different dimensions would be appropriate.

Equally, the length of the housing parts 10 and 20 and the positions of the walls 17, 27 are chosen to be appropriate to a particular standard size of a needle. For larger syringes and longer needles, clearly the dimensions of the needle protector according to the invention would be proportionately increased. For ease of gripping when closing the housing parts to protect and enclose a needle, ribs 18 and 28 respectively are included on the outer side of the housing surfaces 12 and 22.

The clip portion 400 is made integral with the housing part 10. It serves to hold the two housing parts in an almost closed position in which they protect a new sterile needle (Fig. 9). At the same time however, it holds the housing parts 10 and 20 a small distance apart and prevents the latch member 15 passing sufficiently through the aperture 25 so that the hook of the latch passes and engages over the edge of the wall 24. If this occurred, it would defeat the object of this embodiment of the invention because a new sterile needle would then be trapped within the closed housing parts 10, 20. However, with the clip 400 in place, this is prevented and yet the needle protector can readily be opened to expose the new needle ready for use by pivoting the clip about its hinge. After use, the housing parts are fully closed and the latching member 15 is then passed through the aperture 25 and trapped by the deflectible part 25a. The protector (enclosing the used needle) can then be safely discarded. This clip portion 400 is illustrated in Figures 5-12. Figures 10 and 12 are partial cross-sections showing a clip portion 400 of the housing part 10 respectively in its closed and open positions. Figure 11 is a perspective view, inverted compared to Figure 10, showing the clip in its open position attached by an integral plastics hinge to the housing part 10. The clip 400 is substantially L-shaped and has limbs 402 and 404 and a lug 406 at the end of the limb 404 nearer to the integral hinge 408. A rib 410 on the outer side of the limbs 402, 404 gives the clip stiffness against deformation. The clip has a stud or rib 412

-6-

towards the free end of its limb 402 which can engage with a stud or rib 12A on the base wall 12 of the housing part 10. The interengagement of these two ribs keeps the clip portion 400 in its closed condition, and the lug 406 on the clip then prevents the latch member 15 moving to its permanently-locked position. However, by flicking back the clip 400 to the position shown in Figure 11, the latch member 15 is freed to pass through the slot 25 and take up a locked position. The closed protector can then be discarded, with no fear that the infected needle can be extracted therefrom (except of course by total destruction of the protector). In the closed position of the clip 400, seen in Figure 9, it will be observed that the limb 402 and its rib 412 embrace and engage with the end of the housing part 10 and its rib 103 while the lug member 406 prevents full closure of the housing parts 10, 20.

The reference numerals used in this description from this point on are those shown in Figs. 1-4 and 13.

Referring now to Figure 13, a needle protector 400 according to any one of the U.K. pending patent applications Nos. 8928957, 8928956 and 8928959 has a pair of housing parts 402, 404 which are joined by integral plastics hinges to a central part 406 which is square or rectangular as seen in end view looking in the direction of the other 408 in Figure 10. The housing parts each have two opposed side walls, one of each pair seen at 410, 412, and end walls 414, 416, and can be mutually closed together to define, together with the central part 406, a substantially closed chamber. As seen in Figure 10, the protective cap 112 is in the course of being removed just prior to insertion of the needle. However, before this stage is reached the holder 120 is fully screwed up tight to the boss 116 clamping the wall 418 of the central part 406 firmly between the end surface 118A of the collar 118 and the surface 116A of the boss 116.

The needle 122A is then inserted into the patient and the receiver 130 pushed onto the needle portion 122B, resulting in the taking of a sample in the manner conventional with the familiar "Vacutainer" system. Once the needle portion 122A is withdrawn, the benefit of the present invention is realised, because the two housing parts 402, 404 are closed together until they snap lock shut by simple squeezing between thumb and finger, while the

-7-

remaining fingers, or the other hand, continue to hold the syringe-like holder 120. This squeezing can easily be done without ever bringing the fingers or any part of the nurse's body close to the tip of the withdrawn needle portion 122A. Moreover, as more fully described in U.K. Patent Application No. 89 28957.3, the two housing parts, once closed, fully enclose the needle and stay locked together unless subjected to extreme abuse.

Thus for the first time there is made available, by the combination of the established "Vacutainer" system with a needle protector in the manner disclosed herein, a substantially fully-safe method of blood sampling which can be carried out one-handed if necessary.

CLAIMS

1. A blood sampling kit comprising:-
an open ended syringe barrel, a double ended needle having a central boss and one end closable by a removable sleeve, a blood sample receiver closed by a puncturable membrane and containing sterile gas at a pressure substantially negative relative to atmospheric, and a needle protector having a central part attached to or clipped on to the central boss, the protector being hingeable between closed and open positions and when closed defining a substantially closed chamber for containing part of a needle.
2. A kit according to claim 1 in which the protector is closable in a non-return manner so as to substantially encase a used needle to render repeat use thereof substantially impossible.
3. A blood sampling kit according to claim 2 in which the needle protector is of synthetic plastics material and has a pair of housing parts joined to the central part by integral plastics hinges, and in which a clip is attached to one of the housing parts and is pivotable between an almost closed position and an open position, the clip in its almost closed position holding the housing parts together but a small distance apart.
4. A method of taking a sample of blood from a patient which comprises utilising the well-known "Vacutainer" system characterised in that a needle protector in accordance with either of U.K. Patent Application Nos. 89 28959 or 89 28957 is applied to the central boss of the double needle of the "Vacutainer" system.
5. A blood sampling kit of the "Vacutainer" type characterised in that a needle protector according to either of U.K. Patent Application Nos. 89 28959 and 89 28957 is attached to the central boss of the double needle to protect one end of the double needle prior to use.
6. A blood sampling kit substantially as herein described with reference to and as illustrated in the accompanying drawings.
7. A method of using a "Vacutainer" blood sampling kit substantially as herein described with reference to and as illustrated in the accompanying drawings.

1/5

FIG.1.

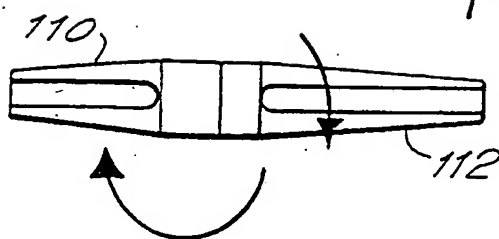


FIG.2.

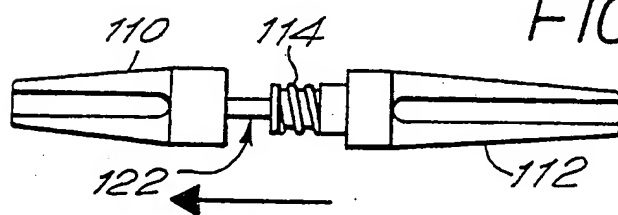


FIG.3.

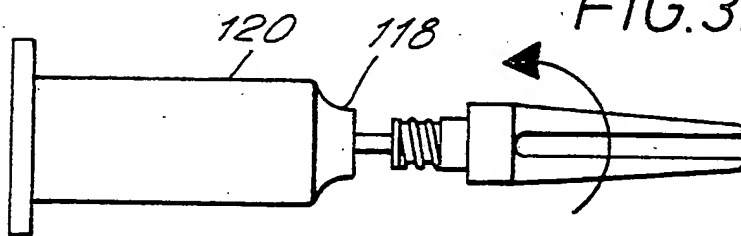
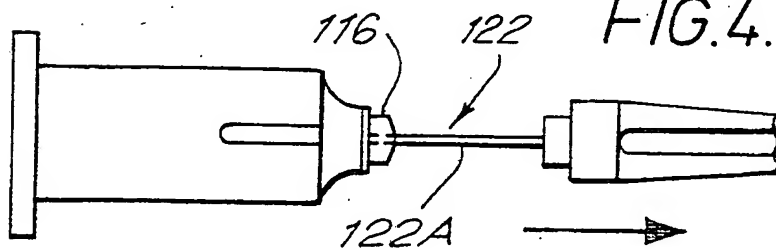


FIG.4.



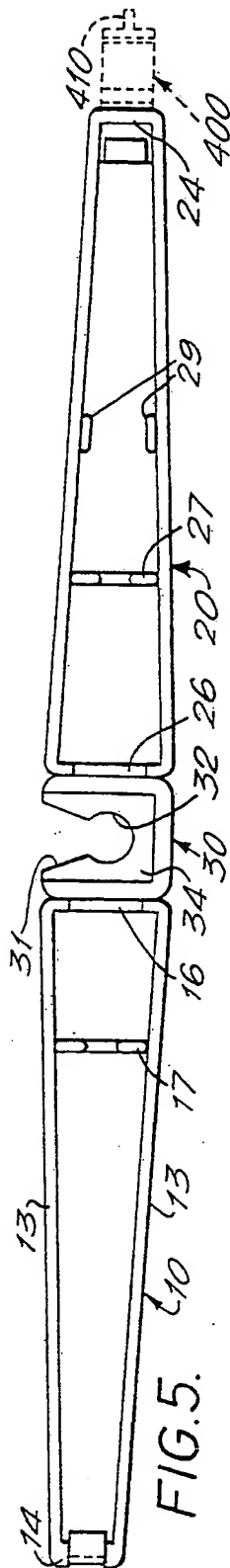


FIG. 5.

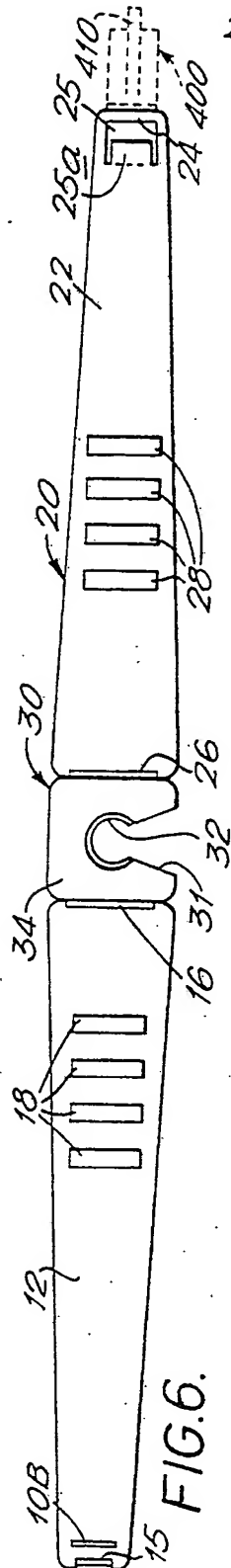


FIG. 6.

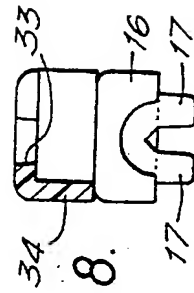


FIG. 8.

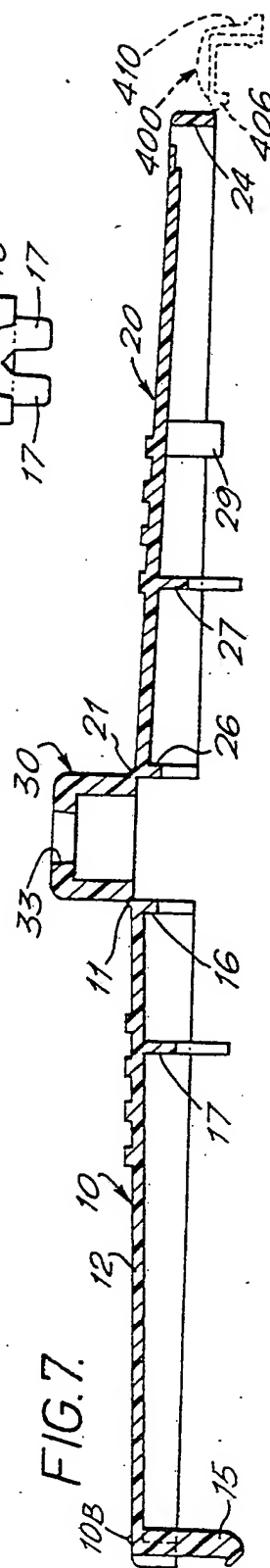


FIG. 7.

3/5

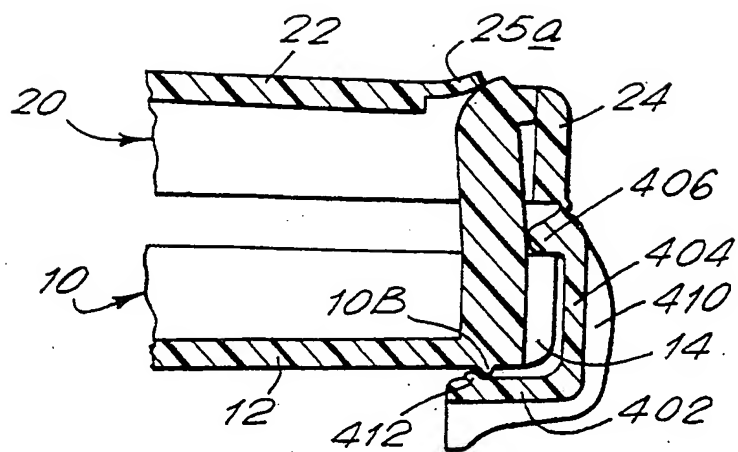


FIG. 9.

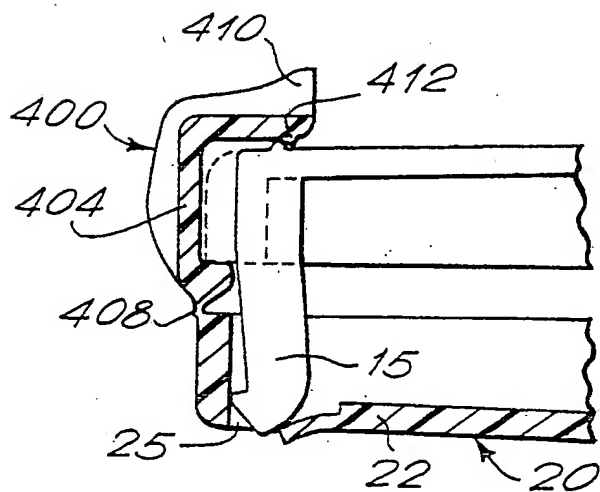


FIG. 10.

4/5

FIG.11.

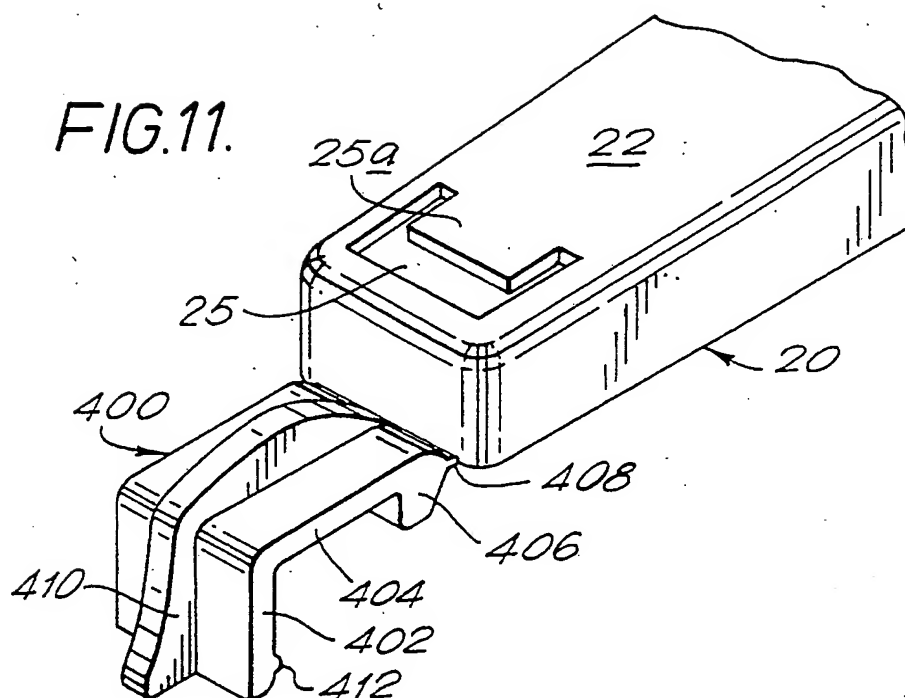
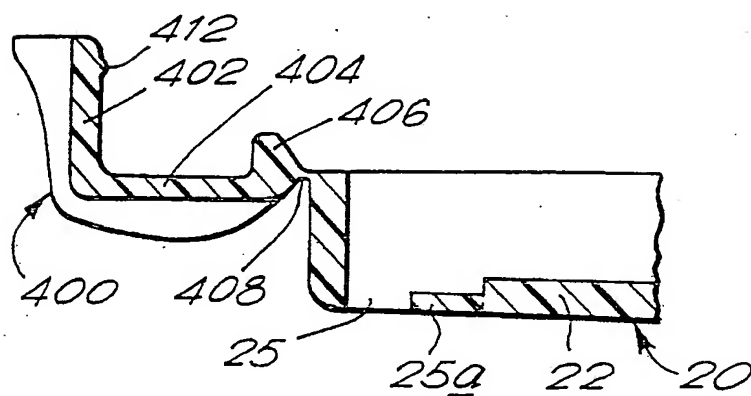


FIG.12.



5/5

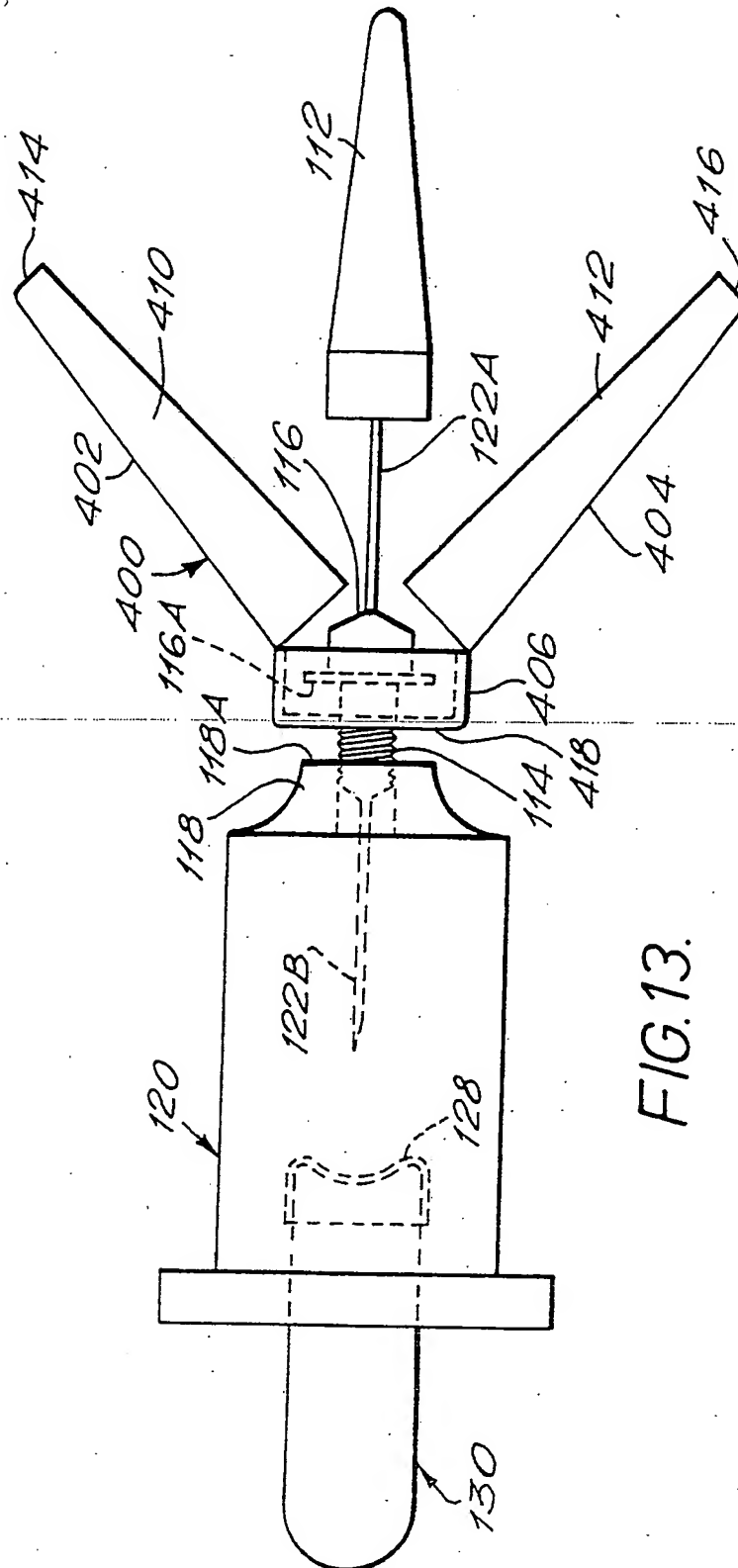


FIG. 13.

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 90/01993

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC ⁵ : A 61 M 5/32, A 61 B 5/14		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification-System	Classification Symbols	
IPC ⁵	A 61 M	
Documentation Searched other than Minimum Documentation to the extent that such documents are included in the fields searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y	US, A, 4886503 (MILLER) 12 December 1989 see abstract; column 1, line 55 - column 2, line 9; figures 12-14 --	1,2
Y	GB, A, 1297183 (JOHNSON & JOHNSON) 22 November 1972 see page 1, lines 11-24, 58-86; figures 1-9 --	1,2
A	WO, A, 8907954 (HABLEY MEDICAL TECHNOLOGY) 8 September 1989 see abstract; page 13, lines 3-19; figures 1-21 --	1-3
A	WO, A, 8802638 (WANDERER) 21 April 1988 see abstract; column 2, lines 42-62; figures 6,7,15-18 -- ./.	1-3
<p>* Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"Z" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
20th March 1991	- 6. 05. 91	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	M. PEIS <i>M. Peis</i>	

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	US, A, 4820277 (NORELLI) 11 April 1989 see abstract; column 2, lines 42-62; figures 6,7,15-18 -----	1-3
---	---	-----

V. ☒ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claim numbers xx, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

xx Claims 4 - 7 not searched.

pls. see attached sheet ./.

3. ☐ Claim numbers because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION C NTINUED FROM

Rule 6.2 (a): References to Other Parts of the Int. Application
Claims shall not, except where absolutely necessary, rely, in respect of the technical features of the invention, on references to the description or drawings. In particular, they shall not rely on such references as: "as described in part ... of the description," or "as illustrated in figure ... of the drawings."

Rule 6.3 (a): Manner of Claiming

The definition of the matter for which protection is sought shall be in terms of the technical features of the invention.

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

GB 9001993
SA 43249

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 19/04/91. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4886503	12-12-89	US-A- 4944397	31-07-90
GB-A- 1297183	22-11-72	DE-A, B, C 2028662	07-01-71
		SE-B- 377967	04-08-75
WO-A- 8907954	08-09-89	US-A- 4867172	19-09-89
		EP-A- 0362333	11-04-90
		JP-T- 2503281	11-10-90
WO-A- 8802638	21-04-88	US-A- 4731059	15-03-88
		US-A- 4693708	15-09-87
		AU-A- 7439987	06-05-88
US-A- 4820277	11-04-89	AU-A- 2983389	17-08-89
		DE-A- 3904559	24-08-89
		FR-A- 2627088	18-08-89
		GB-A- 2215612	27-09-89
		JP-A- 1268563	26-10-89
		US-A- 4909792	20-03-90
		US-A- 4909791	20-03-90

EPO FORM 1077

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82